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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,265	12/10/2001	Yumio Kudo	1110-0305P	6012

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 07/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/009,265	Applicant(s) KUDO ET AL.	
	Examiner Gollamudi S Kishore, Ph.D	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-11,13 and 15-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-11,13 and 15-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The filing of RCE dated 3-15-04 is acknowledged.

Claims included in the prosecution are 1, 3-11, 13 and 15-19.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 3-11, 13 and 15-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is confusing (also in claims 18 and 19). If the composition is meant for the delivery of the active agent to the large intestines, then how can the enteric coating be optional? Furthermore, the disulfide bond in cystine is susceptible to the strong acidic environment of the stomach if the product is not enterically coated. The examiner suggests the removal of 'optionally'. The examiner also suggests reciting the lower limit of the pH in (2) of claim 1 (also in claims 18 and 19) since it is confusing.

Claim 10 is confusing. Claim 1 product is a layered product wherein the coating underneath the enteric coating is a matrix with particles in it and is meant for enteric delivery. Claim 10 however, recites a film and a coating film. Are the films administered for enteric delivery? If so, how? . It is also unclear what the coating film is intended to convey. To coat what material? What is the distinction between the film and the coating film? They apparently have the same composition.

Claim 19 is confusing. What is meant by 'content' in (1)? Also unclear from the claim is whether the capsule wall has the layers or the contents. The examiner suggests restructuring the independent claims.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 3-4, 8-11, 13-17 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Iida (5,057,317).

Instant product requires a core containing the active agent, coated with particles containing disulfide containing compound (cystine) and a polymer with a molecular weight above 1000 and having EITHER a property of being decomposed by enterobacteria OR being softened, swelled or dissolved in the large intestine and optionally coated with an enteric coating.

Iida discloses a product, which contains a core containing an active agent, which is surrounded by particles of cystine, hydroxypropylmethyl cellulose (swellable polymer) mixture. The product is further coated with an enteric coating. The product can be in form of a capsule. The cystine-polymer layer further contains an additional release control agent, adenine (note abstract,

Art Unit: 1615

Example 4 on columns 7-8). Although lida does not explicitly state the molecular weight of the polymer to be more than 1000, since celluloses are polysaccharides with a minimum degree of polymerization of 1000 monomers, such molecular weight is implicit. The reference meets the requirements of instant claims.

Hawley's condensed chemical dictionary is cited regarding the molecular weight (page236).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 3-11, 13 and 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over lida cited above in combination with Lo (5,516,530) by itself or in combination with Watanabe (6,368,629) of record.

As pointed out above, instant product requires a core containing the active agent, coated with particles containing disulfide containing compound (cystine) and a polymer with a molecular weight above 1000 and having EITHER a property of being decomposed by enterobacteria OR being softened, swelled or dissolved in the large intestine and optionally coated with an enteric coating.

Art Unit: 1615

The teachings of Iida have been discussed above. What is lacking in Iida is the teaching of chitosan as the polymer instead of Hydroxypropylmethyl cellulose.

Lo while disclosing tablet formulations teaches that film forming polymers such as hydroxypropylmethyl cellulose or chitosan, and pectin could be used (col. 3, lines 34-50).

Watanabe as extensively discussed before, teaches that chitosan in colon specific drug delivery tablets reacts with enterobacteria in the lower part of the gastrointestinal system with the subsequent delivery of the active agent (abstract).

The use of chitosan instead of hydroxypropylmethyl cellulose taught by Iida would have been obvious to one of ordinary skill in the art because Lo teaches that both are film-forming polymers. One of ordinary skill in the art would be motivated further to use chitosan for its property of reacting with enterobacteria in the lower part of the gastrointestinal system and thus, useful in colon specific drug delivery devices as taught by Watanabe.

The reference of Edgren which teaches cystine as enteric material is cited of interest (note col. 4, line 35 through col. 5, line 20).

Applicant's arguments have been fully considered, but are deemed to be moot in view of these new rejections.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S Kishore, Ph.D whose telephone

Art Unit: 1615

number is (571) 272-0598. The examiner can normally be reached on 6:30 AM-4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK